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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,235	06/22/2001	Joan P. Blonder	42830-00234	8106

25231 7590 07/15/2003

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EXAMINER
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LI, BAO Q

ART UNIT	PAPER NUMBER
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1648  
DATE MAILED: 07/15/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/888,235	BLONDER ET AL.
Examiner	Art Unit	
Bao Qun Li	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 28 April 2003 .

2a) This action is **FINAL**.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1, 4-7,9-31,33-44 and 148-197 is/are pending in the application.

4a) Of the above claim(s) 148-197 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1,4-7,9-31 and 33-44 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. \_\_\_\_\_ .
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .	6) <input type="checkbox"/> Other: _____

## **DETAILED ACTION**

Claims 1, 4-7, 9-31, 33-44 and 148-197 are pending.

### ***Response to Amendment***

This is a response to the amendment, paper No. 11, filed 04/28/03. Claims 1, 4-7, 33-44 have been amended. Claims 2, 3, 8, 32 and 45-147 have been canceled. Claims 1, 4-7, 9-31 and 33-44 are considered by the examiner.

Applicants are reminded to cancel claims 148-197 drawn to the non-elected group.

Please note any ground of rejection(s) that has not been repeated is removed. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

### **Declaration under 37 C.F.R § 1.132**

1. The Declaration of Dr. Claire M. Coeshott under 37 CFR 1.132 filed April 28, 2003 has been acknowledged.
2. The Declaration is sufficient to overcome the rejection of claims 1-44 based upon more evidences provided Dr. Claire M. Coeshott that demonstrate several other antigens rather than Tetanus toxoid (TT), such as diphtheria toxoid (DT), anthrax protective antigen (rPA) if they are combined with the polymer and an adjuvant or CpG motif, produces an enhanced immune response.

### ***Claim Rejections - 35 USC § 102***

3. Claims 1, 4-7, 9-31 and 38-44 are still rejected under 35 U.S.C. 102(e) on the same ground as stated in the previous Office Action as being anticipated by Balasubramanian et al. (a) (US Patent No. 6,086,899A) or by Balasubramanian et al. (b) (US Patent No. 6,416,947B1).
4. Applicants argue that both Patents “899” and 947” are directed to a vaccine composition comprising polypropylene/polyxyethylen block polymer, in which the polypropylene/polyxyethylen block polymer block is used as a new adjuvant and they does not disclose such vaccine formulations having a reveres-thermal viscosity behavior, or even that the novel c-polymer would be useful to impart such reverse-thermal viscosity behavior.
5. Applicants’ argument has been respectfully considered; however, it is not found persuasive because the structure of claimed polypropylene/polyxyethylen block polymer is identical to a polypropylene/polyxyethylen block polymer disclosed by Balasubramanian et al. in

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both patents "899" and 947". Therefore, reverse-thermal viscosity behavior of the same polypropylene/polyxyethylen block polymer is an inherent characteristic of the polymer even if patents "899" and 947" are silent for this. Regarding to the argument of other adjuvant, this limitation is not in the rejected claims. Moreover, the administration of the composition disclosed by "899" and 947" comprising same polypropylene/polyxyethylen block polymer in combination with variety of an antigen produces an enhance immune response by administering it into an animal through variety of routes. Therefore, the rejection is maintained.

6. Claims 1, 4-7, 9-31 and 43-44 are still rejected under 35 U.S.C. 102(b) on the same ground as stated in the previous Office Action as being anticipated by Ron et al. (WO 98/06438A2).

7. In response to the Office Action, Applicants admit that Ron discloses a novel reversibly gelling polymer network and use of the reversibly gelling polymer network for pharmaceutical delivery applications. However, Applicants argue that Ron does not disclose or suggest the every specific combination of elements in the composition for antigen delivery as recited in claim 1, which requires formulation of an antigen and a non-alum adjuvant together with a polyyakylene block copolymer and a liquid with reverse-thermal viscosity behavior.

8. Applicants' argument has been fully considered; however, it is not found persuasive because Ron teach that the same heat sensitive polyyakylene block copolymer in combination with an antigen of a DNA virus and an RNA virus, a bacterium, a tumor or protein antigen, such as tetanus toxoid, peptide antigen etc (see col. 9, line 50 through col. 11, line 64), which meet all limitation of claim 1, whereas the limitation of "a non-alum adjuvant" is not the in the rejected claims. Therefore, the rejection is maintained.

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***Claim Rejections - 35 USC § 103***

9. Claims 1-44 are still rejected under 35 U.S.C. 103(a) on the same ground as stated in the previous Office Action as being unpatentable over Balasubramanian et al. (b) (US Patent No. 6,416,947B), Viegas et al. (a: US Patent No. 5,071,644 and B: 5,593,683), Illum et al (a: Pharmaceutical Research, 1994, Vol. 11, No. 1186-1189), Cox (Vaccine 1997, Vol. 15, pp. 248-256) and Horner et al. (Cellular Immunology 1998, Vol. 190, pp. 77-82) or over Ron et al. (WO 98/06438), Illum et al. (a: Pharmaceutical Research, 1994, Vol. 11, No. 1186-1189), Cox et al.

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(Vaccine 1997, Vol. 15, pp. 248-256), Horner et al. (CELLULAR IMMUNOLOGY 1998, Vol. 190, pp. 77-82).

10. Applicants argue that Office Action appears to pick and choose claimed elements from a number of references and then, apparently using handing sight with the invention as guide, to find obvious the combination of theses elements in the precise manner of the invention.

Applicants further emphasized that the nature of the invention of claims 1-44 is not the discovery of new antigens, new polymers, or new adjuvant, but it rather a very specific and narrow combination of components and a formulation properties for an antigen delivery composition. Moreover, Applicants further argue that examiner has made no showing of why one of ordinary skill in the art would select the specific components recited in claims 1-44 and then combine those specific components in the specific and narrow combination of claims 1-44.

11. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

12. In the instant case, the function of each component, such as heat sensitive polyyakylene block copolymer, an adjuvant of CpG motif and an antigen etc. are all well known in the art. It is also well known in the art that the combination of polyyakylene block copolymer with an antigen or a combination of an adjuvant, such as CpG motif and an antigen into a composition is able to produce an enhanced immune response. Therefore, it is obvious for COMBINING EQUIVALENTS KNOWN FOR THE SAME PURPOSE.

13. Applicants' attentions are directed to the MPEP 2144.06 Art Recognized Equivalence for the Same Purpose. The MPEP says that "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850. The board held that it would have been *prima facie* obvious, within the meaning of 35

846, 850. The board held that it would have been *prima facie* obvious, within the meaning of 35 U.S.C. 103, to employ these components in Combination for their known functions and to optimize the amount of each additive...". Because Applicants have not shown that the claimed invention is an unexpected result, the rejection is still maintained as a *prima facie* obvious absence of unexpected result.

***Conclusion***

No claims are allowed.

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 703-305-1695. The examiner can normally be reached on 7:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Bao Qun Li

July 9, 2003

  
JAMES HOUSEL 7/9/03  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600